



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
09/660,466	09/12/2000	Dinesh Mody	FMT1P029	6579
758	7590	10/20/2004	EXAMINER	
FENWICK & WEST LLP SILICON VALLEY CENTER 801 CALIFORNIA STREET MOUNTAIN VIEW, CA 94041			ROANE, AARON F	
			ART UNIT	PAPER NUMBER
			3739	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,466

Applicant(s)

MODY ET AL.

Examiner

Aaron Roane

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-39, 41-46, 48-87 and 89-110 is/are pending in the application.
- 4a) Of the above claim(s) 48-50, 52, 54-56, 58-65, 68-75, 77, 87, 92-99 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-39 is/are allowed.
- 6) ☒ Claim(s) 36, 41-46, 51, 53, 57, 66, 67, 76, 78-91 and 100-110 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 78-80, 85-87, 89-91 and 105 are rejected under 35 U.S.C. 102(e) as being anticipated by Gough et al. (USPN 5,863,290).

Regarding claims 78-80, 85, 86 and 89-91, Gough et al. disclose a microwave ablation system (see third the paragraph beginning after the "summary of the invention" and the later discussion of the connection to the microwave energy source 20) as seen in figures 3-8 comprising an ablation device (16) that includes an energy delivery portion and an introducer (14) having a sharpened distal end and that is sized and dimensioned for slidable receipt of the ablation device there through. As seen for example in figure 3 (and

explained in column 6, lines 30-60), the energy delivery device is made of a nitinol material and is selectively deployed to attain multiple shapes and sizes ranging from only “a few degrees from the longitudinal axis” to an obtuse angle embodiment described as a “j-hook” type. Additionally, Gough et al. disclose a device that is fully capable of performing the intended use as claimed, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since no structural limitation is recited the prior art meets the claimed invention.

Regarding claims 82-84, Gough et al. further disclose an antenna (16) device that is preshaped and extends at an angle within the range of 0° and 90° or 45° and 135° with respect to the longitudinal axis of the shaft, see col. 4-6 and figures 1-4. Furthermore, Gough et al. further disclose a dielectric layer (18) encapsulating the antenna (16), see col. 5, lines 23-45 and figures 1-8.

Regarding claim 105, Gough et al. disclose the claimed invention, see col. 1-14 and figures 1-10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36, 41-46, 53, 57, 66, 67, 76, 100-104 and 106-110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al. (USPN 5,863,290) in view of Kasevich (USPN 6,233,490 B1).

Regarding claims 36, 57, 66, 67, 76 and 100, Gough et al. disclose a microwave treatment assembly comprising an elongate microwave antenna device (16), an introducer or elongate probe (14) that carries a portion of the antenna device within a lumen having a sharpened distal end (14') and allowing for the slidable displacement of the antenna device beyond the distal end of the probe, see col. 4-10 and figures 1, 3, 4, 6C, 9 and 10. Gough et al. also disclose a microwave power source; see col. 5, lines 46-57. Gough et al. fail to explicitly recite an antenna device comprising a coaxial cable having an inner conductor, an outer conductor and a dielectric medium separating the inner and outer conductors and the antenna device electrically connected to the distal end of the inner conductor. It is well known that microwave antennas can be connected to the distal end of a coaxial cable having an inner conductor, an outer conductor and a dielectric

medium in order to serve as a waveguide and radiate energy in the microwave frequency range in order to ablate tissue. For example it is well known that waveguides for TEM mode radiation must be in a coaxial form. Kasevich discloses a microwave antenna ablation system comprising a shaft (18) and microwave antennas (22, 24 and 26) coupled to the distal end of a coaxial cables (28, 30 and 32) in order to provide hyperthermal therapy, see col. 4-14 and figures 1-4. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gough et al., as is well known in the art and shown by Kasevich, to provide an alternate means of microwave energy propagation and radiation in the form of a microwave antennas connected to the distal end of a coaxial cable having an inner conductor, an outer conductor and a dielectric medium in order to serve as a waveguide and radiate energy in the microwave frequency range in order to ablate tissue.

Regarding claims 41-43, 101 and 102, Gough et al. further disclose an antenna (16) device that is preshaped and extends at an angle within the range of 0° and 90° or 45° and 135° with respect to the longitudinal axis of the shaft, see col. 4-6 and figures 1-4. Furthermore, Gough et al. further disclose a dielectric layer (18) encapsulating the antenna (16), see col. 5, lines 23-45 and figures 1-8.

Regarding claims 44 and 45, Gough et al. further disclose the nitinol (NiTi) preshaped antennas (16), see col. 5, lines 3-9.

Art Unit: 3739

Regarding claims 46 and 53, Gough et al. disclose the claimed invention. The device disclosed by Gough et al. is fully capable of performing the intended use as claimed, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Since no structural limitation is recited the prior art meets the claimed invention.

Regarding claims 103 and 104, Gough et al. disclose the claimed invention, see above rejection to claims 36, 57, 66, 67, 76 and 100.

Regarding claims 106-110, Gough et al. in view of Kasevich the claimed invention, see Gough et al. col. 4-10 and figures 1, 3, 4, 6C, 9 and 10 and Kasevich col. 4-14 and figures 1-14.

Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al. (USPN 5,863,290) in view of Laird et al. (USPN 6,533,780 B1).

Regarding claim 81, Gough et al. disclose the claimed invention except for making the conductive layer overlying the energy delivery device (antenna) from silver. It is well known in the art to provide electrically conductive materials that are biocompatible, such as silver. Laird et al. disclose an electrosurgical device and uses electrically conducting

Art Unit: 3739

materials such as silver in order to provide biocompatibility between the device and the body, see col. 16, lines 27-47. It should be noted that Laird et al. is simply used to demonstrate that it is well known that electrically conductive materials be made from such metals as silver in order to be compatible with the biological surroundings.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gough et al., as is well known in the art and shown by Laird et al., to make the conductive layer overlying the energy delivery device (antenna) from silver in order to provide biocompatibility between the device and the surrounding biological environment.

Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gough et al. (USPN 5,863,290) in view of Kasevich (USPN 6,233,490 B1) as applied to claim 36 above, and further in view of Guzaik et al. (USPN 6,162,216).

Regarding claim 51, Gough et al. in view of Kasevich disclose the claimed invention except explicitly reciting that the shaft has a diameter of 3mm or less. It is well known in the art to provide an electrosurgical device that has a shaft (i.e. a catheter-type instrument) with an appropriately sized diameter in order to facilitate treatment of the biological area. Guzaik et al. disclose an electrosurgical ablation device having a shaft (20) having a diameter well within the recited range ("approximately 0.7 to 2.7 mm," see col. 4, lines 1-14) in order to facilitate the placement of the device, see col. 7-8.

Therefore at the time of the invention it would have been obvious to one of ordinary skill

in the art to modify the invention of Gough et al. in view of Kasevich, as is well known in the art and shown by Guzaik et al. to size the diameter of the shaft between “approximately 0.7 to 2.7 mm” in order to facilitate the placement of the device.

Allowable Subject Matter

Claims 37-39 are allowed.

Response to Arguments

Applicant's arguments filed 7/12/2004 have been fully considered but they are not persuasive.

Beginning with the comments directed to the 102 rejections to claims 78-80, 85-87 and 89-91 on page 12, as the antennas 16 are deployed they deflect and are capable of substantially conforming to inner wall of a heart. In fact, Gough et al. do not disclose the treatment on a heart. However, the device disclosed by Gough et al. is perfectly capable of performing the claimed function. With respect to claim 80, when the antennas are retracted they are enclosed within the larger antenna 14, which is comprises a conductive layer and overlays the antennas 16. Finally,

Art Unit: 3739

the dielectric layer 18 does encapsulate or equivalently cover the antennas 16. Although, 18 is not axially fixed with respect to 16, it does encapsulate/cover the antennas 16.

Regarding the rejections to claims 36, Gough et al. do disclose an antenna 16 that is deployed in a straight configuration and at angle with respect to the introducer 14, see figure 2. Again, with respect to the recited encapsulation, the dielectric layer 18 does encapsulate or equivalently cover the antennas 16. Although, 18 is not axially fixed with respect to 16, it does encapsulate/cover the antennas 16. Applicant states that neither Gough et al. nor Kasevich disclose an antenna coupled to the inner conductor of a coaxial conductor. This is incorrect. Kasevich discloses that use of a coaxial conductor (with inner and outer conductors) and show the antenna coupled to the distal end of its inner conductor.

Regarding the rejection to claim 57, Applicant argues that both Gough et al. and Kasevich are silent as to the treatment and penetration of a heart. As set forth by the language of claim 57, Gough et al. in view of Kasevich is fully capable of performing the recited function. Again it should be noted that a recitation of intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Additionally, the functional language does not distinguish over the prior art.

Regarding the rejection to claim 76, the combination of Gough et al. and Kasevich is well motivated and certainly discloses the coaxial arrangement of the antennas, in addition to it being extremely well known in the art to use a coaxial arrangement when using microwave energy to treat tissue. Secondly the recitation that "it is generally believed that the radiated field tends to be more confined along the antenna device 30 when the distal end of the outer conductor 32 is extended in the organ cavity and exposed to the surrounding medium" offers no support to Applicant's argument since confinement of radiation fields is a well known naturally occurring phenomenon.

Regarding claim 100, Gough et al. discloses a device that conforms to the inner wall of the treatment tissue. The antennas 16 are deployed and are capable of conforming to the inner walls of an organ since they are flexible and provided in a straight or curved configuration.

Regarding claim 81, the addition of Laird et al. is used to teach the covering of electrosurgical devices with a biocompatible material. The fact that Laird et al. do not disclose coating Niti with a biocompatible material is one reason why Laird et al. was not used in a 102 rejection. The recited Niti is recited by Gough et al. and is part of the reason Laird et al. was combined with Gough et al..

Regarding claim 51, Gough et al. in view of Kasevich and further in view of Guzaik et al. were used in combination to meet the recited diameter of less than 3 mm. Additionally the previous office action contained a typographical error in 103 section addressing claims 36, 41-

Art Unit: 3739

46, 53, 57, 66, 67, 76 and 100-104 rejected by Gough et al. (USPN 5,863,290) in view of Kasevich (USPN 6,233,490 B1) which mistakenly contained an incomplete rejection of claim 51. However, claim 51 was properly rejected by Gough et al. in view of Kasevich and further in view of Guzaik et al., a rejection which is reaffirmed.

This action is Final.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Art Unit: 3739

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. *A.R.*
October 17, 2004

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER